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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,878	12/09/2003	Ruchika Singhal	1023-334US01	4796
28863	7590	07/18/2006	EXAMINER	
SHUMAKER & SIEFFERT, P. A. 8425 SEASONS PARKWAY SUITE 105 ST. PAUL, MN 55125			KAHELIN, MICHAEL WILLIAM	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

C

Office Action Summary	Application No. 10/730,878	Applicant(s) SINGHAL ET AL.	
	Examiner Darin R. Roberts	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/21/06; 9/29/05</u> | 6) <input checked="" type="checkbox"/> Other: <u>6/20/05; 10/29/04</u> |

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 10, 13, 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kirkpatrick et al. (US 6480743 B1 hereinafter "Kirkpatrick et al. patent").

In reference to claims 1 & 14, the applicant argues that the definition of an overmold used by the examiner is a mischaracterization however the term overmold is a somewhat broad term and does encompass the housing of the Kirkpatrick et al. device. The Kirkpatrick et al. patent teaches a device possessing an overmold, this overmold is referred to as a housing (see column 9, lead lines 8-11). The Kirkpatrick et al. patent also teaches the use of a battery (see column 9, lead line 13) as well as a microcontroller (see column 13, lead lines 43-45), each inherently possessing respective housings to contain their respective components. The battery and the microcontroller are connected via a power transferring means.

In reference to claim 2, the Kirkpatrick et al. patent teaches the use of a microcontroller, which inherently possesses electronic components.

In reference to claims 3, 4, & 10, the Kirkpatrick et al. patent teaches an overmold possessing a first material referred to as titanium (see column 9, lead lines 8-11). The lead connection module cannot merely exist on the surface of the implantable device, it must, in some way, penetrate the overmold to communicate with the inner components of the device of the Kirkpatrick et al. patent, thus the lead connection

module must at least partially exist within the overmold of the Kirkpatrick et al. device (see fig. 2 & column 8, lead lines 47-54). Titanium is also inherently a non-elastomeric material.

In reference to claim 5, the Kirkpatrick et al. patent teaches the use of a feed through wire referred to as a conductor (see column 8, lead lines 49-52).

In reference to claim 6 & 7, the lead connection module of the Kirkpatrick et al. patent also possesses a mechanical lead securing mechanism that is tool-less (see fig. 2 & column 8, lead lines 47-54)

In reference to claims 9 & 13, the examiner believes that the Kirkpatrick et al. patent teaches all of the limitations found in claims 9 and 13. The Kirkpatrick et al. patent teaches the use of an overmold (see column 9, lead lines 8-11) for a modular implantable medical device that includes a plurality of modules, each of the modules comprising a respective housing (see column 9, lead line 13 & column 13, lead lines 43-45). The overmold of the Kirkpatrick et al. patent comprising a first material is configured to hold at least part of the housing of one of the modules as well as a lead connection module configured to accept an external lead (see fig. 2), the lead connection module being deployed within a first material of the overmold, and the lead connection module being made of a second biocompatible material (see column 8, lead lines 47-54).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8, 11, & 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirkpatrick et al. (US 6480743 B1, hereinafter "Kirkpatrick et al. patent").

In reference to **claim 8**, the Kirkpatrick et al. patent teaches the use of an implantable medical device, however the Kirkpatrick et al. patent does not teach the exact thickness parameters as specified in claim 8.

The Kirkpatrick et al. patent discloses the claimed invention except for the exact thickness parameters as specified in claim 8. It would have been obvious to one having ordinary skill in the art to in the art at the time the invention was made to modify the implantable device as taught by the Kirkpatrick et al. patent with the thickness

parameters as specified in claim 8 since it was known in the art that adapting the thickness of an implant can provide the wearer with a less intrusive device.

It would have also been obvious to one having ordinary skill in the art at the time the invention was made to modify the width of the implantable device as taught by the Kirkpatrick et al. patent since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105USPQ 233.

In reference to **claims 11 & 12**, the examiner realizes that there was no mention of the use of elastomeric materials that is why the rejection of claims 11 and 12 are under a 103 (a) obviousness rejection, not a 102 (a, b, or e) lack of novelty rejection. Kirkpatrick et al. patent teaches the use of an overmold possessing a second material, however the Kirkpatrick et al. patent does not teach the use of a second material consisting of an elastomeric material such as silicone.

The Kirkpatrick et al. patent discloses the claimed invention except for the use of an elastomeric material such as silicone. It would have been obvious to one having ordinary skill in the art to in the art at the time the invention was made to modify the implantable device as taught by the Kirkpatrick et al. patent an elastomeric material such as silicone since it was known in the art that biocompatible materials must be used when constructing an implantable device.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The examiner also wishes to site Jenson et al. (US 6805998 B2, hereafter "Jenson et al. patent"). The Jenson et al. patent teaches the use of multiple modules referred to as battery cells all of which are electrically connected and inherently possess electrical components and individual casings. These modules are encased within a mold that can be referred to as an overmold, said mold can possess pin capable of (see fig. 27C; column 37, lead lines 57-67; & column 38, lead lines 1-8).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571)272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 3762

D. R.


Jeffrey Jastrzab
Primary Examiner
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7/9/06